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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,073	01/30/2006	James T. Wolter	58719US010	2163

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EXAMINER	
CRAIGO, WILLIAM A	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
09/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/595,073	WOLTER ET AL.	
	Examiner	Art Unit	
	WILLIAM CRAIGO	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *1-34 and 52-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *16 March, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group IV, claims 35-51 in the reply filed on 19 July, 2010 is acknowledged.

Claims 1-34 and 52-60 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03 October, 2009.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 16 March, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Status of the Claims

Claims 35-51 are treated on the merits in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The claims are directed to contacting a biological barrier with a microneedle device comprising at least one microneedle that penetrates the barrier no more than 500 microns; administering an immune response modifier (IRM) compound that is a TLR 6, 7, 8, and/or 9 agonist into or across the barrier. Thus the scope of instant claims 35-45 are limited only by functional language, there is no recitation of the structure required to meet the functional limitations in the claims. The scope of instant claims 46-51 limits the IRM compound that is a TLR 6, 7, 8 and/or 9 agonist to a broad genus of imidazoquinoline amine derivatives While applicant's disclosure correlates the structures of three imidazoquinoline amines with the function recited, see applicant's specification paragraph [0071]; and lists a structure CpG known to be correlated with TLR9, see Krieg, Trends in Immunology, Col. 23, 2002 cited in the restriction requirement, there are no other structure function relationships disclosed in the specification, i.e., there are no other imidazoquinoline amine derivative structures which are correlated with TLR 6, 7, 8 and/or 9. The disclosure does not appear to contain even a single species of the genus 4-aminopyrimidine fused to a five membered nitrogen containing heterocyclic ring as recited in instant claim 51 correlated to any function recited in the instant claims particularly a TLR 6, 7, 8 and/or 9 agonist..

"For each claim drawn to a genus: The written description requirement for a claimed genus may be satisfied through sufficient description of a representative

number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

To support claims drawn to a genus, the disclosure must include either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.

The determination of a representative number of species can rest on the predictability of the art. In the instant case, applicant's specification lists three compounds from paragraph [0071]; Examples of particular IRM compounds include 2-propyl[1,3]thiazolo[4,5-c]quinolin-4-amine, which is considered predominantly a TLR 8 agonist (and not a substantial TLR 7 agonist), 4-amino-.alpha.,.alpha.-dimethyl-1H-imidazo[4,5-c]quinoline-1-ethanol, which is considered predominantly a TLR 7 agonist (and not a substantial TLR 8 agonist), and 4-amino-2-(ethoxymethyl)-.alpha.,.alpha.-dimethyl-6,7,8,9-tetrahydro-1H-imidazo[4,5-c]quinoline-1-ethanol, which is a TLR 7 and TLR 8 agonist. As evidenced by this list, the structure to function map provides very few species of the possible compounds encompassed by the genus claimed. Further the disclosure shows that small differences in structure can have significant effects on the functional characteristics of the compounds; showing that differences among the

species of the genus claimed would not predictably correlate with a specific TLR specificity or even activity.

Based on the factors discussed above it is clear that the specification does not disclose a representative number of species to support the scope of the instant claims.

Claims 35-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, the claims contain acronyms. The phrase or words the acronyms represent should be spelled out in the claims at least once.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomai, US 20030133913 in view of Allen, US 6334856 and Babiuk, Journal of Controlled Release, 66, 2000.

Tomai is directed to a method of inducing antigen presentation by dendritic cells in vitro, the method including: (a) exposing an isolated dendritic cell population to an antigen; (b) contacting the isolated dendritic cell with an immune response modifier molecule that is an agonist of Toll-like receptor 6, Toll-like receptor 7 or Toll-like receptor 8; and (c) allowing the dendritic cell to process and present the antigen. In this aspect of the invention and in all additional aspects that follow, for some embodiments the immune response modifier molecule is an agonist of Toll-like receptor 7, and in other embodiments, the immune response modifier molecule is selected from the group consisting of imidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, 1,2-bridged imidazoquinoline amines, thiazolo- and oxazolo-quinolinamines and pyridinamines, imidazonaphthyridine amines and tetrahydroimidazonaphthyridine amines, and pharmaceutically acceptable salts thereof (compare instant claims 35, IRM compound that is a TLR 6, 7, 8 and/or 9 agonist; 46,

one IRM compound is a small molecule immune response modifier, 47-48, imidazopyridine amine. Tomai, [0025], teaches IRM compounds comprising a 4-aminopyrimidine fused to a five membered nitrogen containing heterocyclic ring, see Formula 1, wherein R21 is H, compare instant claims 49-51. Tomai teaches administering a therapeutically effective dose of the cellular adjuvant to the patient.

Tomai does not teach the step of contacting a biological barrier with a microneedle device comprising at least one microneedle that penetrates the barrier by no more than 500 microns.

Allen is directed to microneedle devices for transport of therapeutic and biological molecules across tissue barriers such as for drug delivery, Background, col.1, lines 20-22. Allen teaches contacting a biological barrier with a microneedle device, see for example col. 8, lines 51-65, microneedle device inserted into the skin; Allen teaches microneedle lengths of preferably between 10 microns and 500 microns, meeting the limitation of penetrates the barrier by no more than 500 microns. Allen teaches the device can be used to deliver vaccines, see for example col. 6, lines 30-32.

Babiuk is directed to cutaneous vaccination: the skin as an immunologically active tissue and the challenge of antigen delivery (title). Babiuk expressly teaches the skin may be one of the best sites for vaccination. Babiuk provides a showing that throughout the viable epidermis, immune competent dendritic cells are found. Dendritic cells initiate specific immune responses by presenting the processed antigens to other cells of the immunce system. Babiuk teaches that dendritic cells induce immunity to the foreign antigens they encounter in the skin. Babiuk, pg. 203, provides express

suggestion that microneedle devices can be used to deliver antigens to the epidermis and therefore expose them to dendritic cells in vivo.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the prior art teachings of Tomai, Allen and Babiuk according to known methods to yield the predictable result of providing a method as instantly claimed because Tomai provides a showing that the immune response modifiers which are TLR 6, 7, or 8 agonists in combination with an antigen can be used to stimulate a specific immune response to the antigen (i.e. TLR 6, 7, and 8 agonists can be used as vaccine adjuvants). Allen provides a showing that microneedle devices as instantly claimed were known and used substantially the same as instantly claimed to deliver vaccines by contacting microneedles as claimed with biological barriers. Babiuk provides a showing and express suggestion that the method of contacting a biological barrier as instantly claimed and taught in Allen could be used to deliver vaccines to dendritic cells and stimulate specific immune responses to antigens. Thus the prior art teachings provide a showing that the methods of Tomai could be improved by combination with the methods and devices taught by Allen in a predictable way because the specific immune response could be induced by using the microneedles to deliver the antigen and immune response modifying compounds directly to the dendritic cells in vivo with the expectation of success. The skilled artisan would have been motivated to combine the teachings as claimed because the combination provides a much simpler and less invasive method for inducing the desired immune response.

It would have been prima facie obvious to contact the microneedle device prior to contacting the skin with at least on IRM compound applied topically to the skin in a solution ointment gel or foam (instant claims 36-39) because Allen expressly teaches the drug may be transported through pathways created by microneedles in the skin. Thus there is express suggestion that contacting the barrier with the microneedles provides a conduit through which the drug can pass from the surface. Similarly the topical application of compounds is usually done in a carrier such as a solution to enhance penetration of the compound.

It would have been prima facie obvious to contact the skin with at least one IRM compound applied topically in a solution ointment, gel, foam or emulsion prior to or coincident with contacting the skin with the microneedle device for the same reasons (instant claims 40-44).

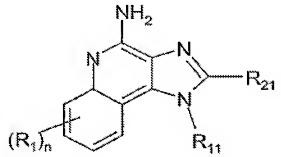
Accordingly, the subject matter of instant claims 35-51 would have been prima facie obvious to one of ordinary skill at the time the invention was made, particularly in the absence of evidence to the contrary.

Claims 35-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomsen, WO02/24225 A1 in view of Allen, US 6334856.

Thomsen is directed to the use of Immidazoquinolineamines as adjuvants in DNA vaccination (title). Thomsen, for example pg. 3, teaches a composition comprising an adjuvant component comprising an imidazoquinoline-4-amino derivative and an immunogenic component comprising a nucleotide sequence encoding an antigenic peptide or protein wherein the adjuvant component enhances the immune response.

Thomsen, pg. 4 teaches 1-(2-hydroxy-2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine and a genus of compounds, for example formula I:

(I)



meeting the limitations of instant claims 46-50. The compounds comprise derivatives of imidazopyridine amines, 1H-imidazopyridines, and a 2-aminopyridine fused to a five membered nitrogen containing heterocyclic ring. Thomsen, pg. 4, teaches simultaneous or sequential administration of the nucleic acid encoding an antigen and an imidazo[4,5-c]quinolin-4-amine derivative. Thomsen, pg. 27, teaches intradermal or topical routes of administration.

Thomsen does not expressly teach the functional activity of the compounds in relation to toll like receptors 6, 7, 8 and/or 9; however as the compounds are the same as instantly claimed, the functional limitations are inherently met because compounds and their properties are inseparable.

While Thomsen teaches intradermal and topical administration of the composition, Thomsen does not expressly teach the step of contacting a biological barrier with a microneedle device as recited in instant claim 35.

Allen is directed to microneedle devices for transport of therapeutic and biological molecules across tissue barriers such as for drug delivery, Background, col.1, lines 20-22. Allen teaches contacting a biological barrier with a microneedle device, see for example col. 8, lines 51-65, microneedle device inserted into the skin; Allen teaches microneedle lengths of preferably between 10 microns and 500 microns, meeting the limitation of penetrates the barrier by no more than 500 microns. Allen teaches the device can be used to deliver vaccines, see for example col. 6, lines 30-32.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the prior art teachings of Thomsen and Allen according to known methods to yield the predictable result of providing a method as instantly claimed because Thomsen teaches a method of inducing a specific immune response by administering the composition as instantly claimed intradermally and/or topically and Allen teaches a microneedle device and the step of contacting the skin with the microneedle device as a method of intradermal administration. Allen also teaches the contacting of the barrier improves the method of administration by providing a conduit to the epidermis whereby the drug compositions can more easily pass through the barrier presented by intact skin.

Accordingly, the subject matter of instant claims 35-50 would have been prima facie obvious to one of ordinary skill at the time the invention was made, particularly in the absence of evidence to the contrary.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomsen, WO02/24225 A1 in view of Allen, US 6334856 as applied to claims 35-50 above, and further in view of Isobe, US 6376501.

In addition to the teachings outlined above, Thomsen teaches DNA vaccination is sometimes associated with an inappropriate deviation of immune response from a Th1 to a Th2 response, particularly when the DNA is administered directly to the epidermis.

Thomsen and Allen are silent 4-aminopyrimidine fused to a five-memberd nitrogen-containing heterocyclic ring as recited in instant claim 51; however such compounds were known in the art.

Isobe is directed to pharmaceutical compositions comprising as an active ingredient a compound having purine structure, and specifically relates to a type 2 helper T cell (hereinafter abbreviated to "Th2")-selective immune response inhibitor and an immune response regulator. More specifically, the present invention relates to a Th2-selective immune response inhibitor and an immune response regulator which can effectively treat or prevent those diseases attributable to abnormal rise immunize response on the Th2 side (i.e. allergic diseases such as asthma, allergic dermatitis or allergic rhinitis, or autoimmune diseases such as systemic lupus erythematosus) by inhibiting immune response on the Th2 side and enhancing immune response on the type 1 helper T cell (hereinafter abbreviated to "Th1") side. Isobe, formula I, teaches 4-aminopyrimidine compounds, (formula I wherein R6 is amino) are capable of solving the problem presented in Thomsen because they simultaneously enhance the immune

response on the Th1 side, thus providing adjuvant properties, while attenuating the immune response on the Th2 side, minimizing inflammation for example.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the prior art teachings of Thomsen, Allen and Isobe according to known methods to yield the predictable result of providing a method as instantly claimed because Thomsen teaches a method of inducing a specific immune response by administering the composition as instantly claimed intradermally and/or topically and Allen teaches a microneedle device and the step of contacting the skin with the microneedle device as a method of intradermal administration. Allen also teaches the contacting of the barrier improves the method of administration by providing a conduit to the epidermis whereby the drug compositions can more easily pass through the barrier presented by intact skin. Further Thomsen provides a showing that the prior art recognized the problem of inappropriate deviation of the immune response from the Th1 (which is responsible for the stimulated response to the antigen) to the Th2 side (which is not desired because it produces an immune response which can be seen as a side effect such as inflammation) and that the compounds as instantly claimed were known in the art and known to solve the problem of inappropriate immune response. Accordingly the skilled artisan would have been motivated to use the compounds taught in Isobe improve the composition by addressing the problem recognized by Thomsen.

Accordingly, the subject matter of instant claims 35-51 would have been prima facie obvious to one of ordinary skill at the time the invention was made, particularly in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-57 of copending Application No. 10925473 in view of Allen, US 633485. The copending application claims a method of administering an immune response modulator in association with an antigen topically. The claims of the copending application do not expressly teach a method of contacting a biological barrier or the skin with a microneedle device as instantly claimed.

Allen is directed to microneedle devices for transport of therapeutic and biological molecules across tissue barriers such as for drug delivery, Background, col.1, lines 20-22. Allen teaches contacting a biological barrier with a microneedle device, see for example col. 8, lines 51-65, microneedle device inserted into the skin; Allen teaches microneedle lengths of preferably between 10 microns and 500 microns, meeting the limitation of penetrates the barrier by no more than 500 microns. Allen teaches the device can be used to deliver vaccines, see for example col. 6, lines 30-32.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the prior art teachings of Allen with the claims of the copending application according to known methods to yield the predictable result of providing a method as instantly claimed because Allen teaches the step of contacting a biological barrier (the skin) with a microneedle device improves the delivery of topical composition and expressly teaches the step in a method of delivering a vaccine.

Accordingly, the subject matter of instant claims 35-51 would have been prima facie obvious to one of ordinary skill at the time the invention was made, particularly in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CRAIGO whose telephone number is (571)270-1347. The examiner can normally be reached on Monday - Friday, 7:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

/WILLIAM CRAIGO/
Examiner, Art Unit 1615